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# QUALITY ASSURANCE PROJECT PLAN TO SUPPORT THE BIOMONITORING COMPONENT OF THE COMMUNITY HEALTH PROGRAM FOR VASQUEZ BOULEVARD AND INTERSTATE 70 (VBI70) OPERABLE UNIT 1 DENVER, COLORADO

OCTOBER 2004

Prepared by
Colorado Department of Public Health and Environment
and
U.S. Environmental Protection Agency Region 8
Denver, Colorado

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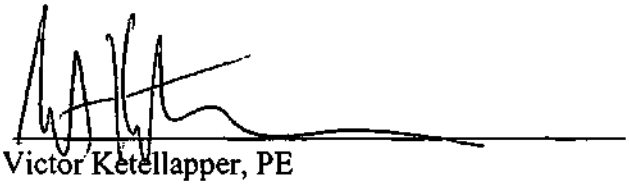
## APPROVAL PAGE

This Sampling and Analysis Plan has been prepared by the U.S. Environmental Protection Agency and the Colorado Department of Health and Environment, with technical support from Syracuse Research Corporation. Sampling and analysis activities addressed in this Plan are approved without condition.



Victor Ketellapper, PE
USEPA Remedial Project Manager

11-1-04
Date

Jane Mitchell, QC Project Manager
CDPHE

Date

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## ATTACHMENTS

## SECTION A. PROJECT MANAGEMENT

### A1. KEY PERSONNEL

The project for which this Quality Assurance Project Plan (QAPP) has been prepared is being sponsored by the USEPA, and is being planned and performed by representatives of a number of local governmental and public health agencies, including the Colorado Department of Health and Environment (CDPHE), Denver Environmental Health (DEH), Denver Health and Hospitals (DHH), and the Northeast Denver Housing Center (NDHC). Many components of this program will be developed in consultation with community representatives and under the oversight of a steering committee chaired by DEH. More detailed descriptions of the duties and tasks assigned to individual agencies are specified in an interagency memorandum of agreement (MOA).

The basic focus of this project is a human exposure biomonitoring program that is part of a larger Community Health Program (CHP) at the Vasquez Boulevard and Interstate 70 (VBI70) Superfund site in Denver, Colorado. A biomonitoring subcommittee, chaired by the Colorado Department of Public Health and Environment (CDPHE), is tasked with overseeing development of a biomonitoring plan, including all testing protocols and the QAPP. The following individuals will serve as key contacts and provide managerial and technical expertise during implementation of the biomonitoring component of this project:

- Victor Ketellapper, USEPA Remedial Project Manager. Mr. Ketellapper will be responsible for providing support to the local agencies that are planning and performing the project.

- Jane Mitchell, CDPHE. Ms. Mitchell will serve as CDPHE's primary technical representative for development of the QAPP, will oversee all components of the arsenic biomonitoring program and help ensure proper coordination with each of the local agencies that are participating in the planning and performance of the project.

- Mishelle Macias, CDPHE. Ms. Macias will oversee coordination of all of the neighborhood-based testing clinics, and will help ensure proper coordination for the lead testing portion of the biomonitoring program with each of the local agencies that are participating in the planning and performance of the project.

- Wendy Hawthorne, NDHC. Ms. Hawthorne will assist with selection of neighborhood-based clinic testing sites, and assist with logistics of sample collection and clinic staffing.

## A2. PROJECT BACKGROUND AND OBJECTIVES

### Project Background

The VBI70 Superfund Site consists of several residential neighborhoods covering approximately 4-square miles. The area is near the locations of three former smelters, and investigations conducted by the USEPA identified over 850 properties in which concentrations of lead and/or arsenic in soil in residential yards exceeded conservative health-based goals.

A record of decision (ROD) was signed in September 2003 to address potential health risks to residents due to soil contamination in the VBI70 area. Under the ROD, EPA will conduct soil removal for all residential yards exceeding 400 mg/kg lead or 70 mg/kg arsenic. Soil cleanup is anticipated to take a minimum of three years to complete. In addition to removal of contaminated neighborhood soil, the ROD also specified that a community-based health program (CHP), including metals biomonitoring and general education, be provided for residents in the affected neighborhoods until soil remediation was completed.

### Project Objectives

EPA's ROD established the following goals and objectives for the CHP:

1. Address risks to residents living on contaminated soils until site cleanup of metals-contaminated soils is complete.
2. Address risks to children with soil pica behavior.
3. Address risks to children exposed to lead from multiple sources.
4. Provide biomonitoring to identify exposure that may be occurring.
5. Provide response actions for all community participants with elevated metals exposure.
6. Provide health education about ways to identify high soil contact behaviors and mitigate risk of exposure to lead and arsenic.

This document focuses on the planning and implementation of the biomonitoring component of the CHP. The biomonitoring program will offer free testing of blood, urine, and hair to screen for levels of lead and arsenic in residents living in each neighborhood within the VBI70 site.

The primary goal of the biomonitoring program is to provide on-going surveillance within the community to provide information to individual families about whether elevated exposure may be occurring in their home environment, and if so, to help identify the sources of those exposures and provide environmental and medical follow-up, as needed. Secondary goals of the biomonitoring program include collection of sufficient biomonitoring data to allow calculation of community-wide summary statistics on exposure levels, and possibly to allow statistical investigation of the relative importance of soil contamination as an exposure source.

The biomonitoring program targets young children because this is the age-group most at risk of exposure from contaminated soils, due to their age-specific behaviors such as crawling, playing outdoors in the soil, and mouthing objects which may have come into contact with contaminated soil or dust. Young children who exhibit pica or dirt-eating behaviors present a particular concern for potentially having high acute exposure to metals-contaminated soil.

In cases where biomonitoring data indicate an elevated exposure to lead or arsenic is occurring, health coordinators will work with families to help identify the likely exposure source and provide guidance to the family on ways to mitigate or prevent that exposure. Program managers will coordinate with other agencies able to provide additional services to the family to address exposure sources believed to be contributing to lead and arsenic exposure. Northeast Denver Housing Center (NDHC) will provide paint testing and abatement where appropriate. EPA will also be asked to provide high priority soil cleanup for homes where children have an elevated test result which is believed to be associated with soil or dust levels at their property. Families must provide written consent to share information about their child's test results with agencies other than CDPHE or DHH to receive these additional services.

## A3. PROJECT/TASK DESCRIPTION

The basic tasks that must be performed to achieve the objectives of the biomonitoring program include the following:

- Establishing and staffing sample collection facilities in each neighborhood
- Advertising and recruitment of children into the program in each neighborhood
- Collection and analysis of biomonitoring samples
- Reporting of results to citizens
- Environmental and medical follow-up actions, as needed

## A4. DATA QUALITY OBJECTIVES

Data Quality Objectives (DQOs) are statements that define the type, quality, quantity, purpose and use of data to be collected. USEPA has published a number of guidance documents on the DQO process (USEPA 1994, USEPA 2000, USEPA 2002), and this project plan has been developed in accord with that guidance. In brief, the DQO process follows a seven-step procedure, as follows:

1. State the problem that the study is designed to address
2. Identify the decisions to be made with the data obtained
3. Identify the types of data inputs needed to make the decision
4. Define the bounds (in space and time) of the study
5. Define the decision rule that will be used to make decisions
6. Define the acceptable limits on decision errors
7. Optimize the design for obtaining data in an iterative fashion using information and DQOs identified in Steps 1-6

Following these seven steps helps ensure that the project plan is carefully thought out and that the data collected will provide sufficient information to support the key decisions that must be made. The following sections summarize the application of the DQO process to the biomonitoring program of the VBI70 CHP.

**Step 1. State the Problem**

Individuals residing in some areas of the VBI70 site may be exposed to elevated levels of lead or arsenic in soil or other media. These exposures could be of health concern in some cases. Collection and analysis of blood, urine, and/or hair is one method for identifying individuals who have elevated exposures and identifying individuals whose exposures could be of potential concern.

**Step 2. Identify the Decision**

The basic decision that must be made is whether the biomonitoring results for an individual do or do not suggest that elevated exposures to lead or arsenic are occurring.

**Step 3. Identify Inputs to the Decision**

In order to make this decision, two inputs are required:

- The measured concentration of contaminant (lead, arsenic) in the sample
- An estimate of the range of normal exposure levels

For lead in blood, the USEPA and the CDC have established a concentration of 10 ug/dL as the level of health concern. However, for the purposes of this program, concentrations above 5 ug/dL will be interpreted as an indication that exposures are higher than typical, and additional educational and outreach efforts will be provided for these families by NDHC and by DHH, as determined to be appropriate by the case manager. For arsenic in urine or hair, there is no established level of concern based on health risk, but there are values that indicate exposures that are higher than typical. These values are 20 ug/L for arsenic in urine and 0.2 ug/g in hair. These values are summarized below:

| Chemical | Sample Type | Indicator of Elevated Exposure |
|---|---|---|
| Lead | Blood | > 5 ug/dL |
| Arsenic | Urine<br>Hair | > 20 ug/L<br>> 0.2 ug/g |

**Step 4. Define the Study Boundaries**

Spatial Bounds

The spatial boundaries for the biomonitoring program include all residences located within the boundaries of the VBI70 site. This geographic area includes all or portions of the Elyria/Swansea, Clayton, Cole, Curtis Park, and southwest Globeville neighborhoods.

Temporal Bounds

The biomonitoring program will continue to operate until EPA has completed remedial activities within the residential areas (Operable Unit 1) of the VBI70 site. It is expected that the majority of the activities of the biomonitoring program will occur in the late summer or early fall of each year that the program operates, since this is the time of year when exposure of children to contaminants in outdoor soil are likely to be highest. However, the biomonitoring program will continue to operate throughout the year to ensure that citizens always have access to testing.

**Step 5. Develop a Decision Rule**

An individual will be considered to have normal levels of exposure if none of the biomonitoring samples collected from the individual exceed the normal ranges identified above. If one or more of the samples exceed the normal range, and if the values are confirmed by re-sampling, then the individual will be considered to have a source of exposure that is higher than typical, and follow-up actions may be necessary to identify the exposure and to address any resultant medical concerns.

**Step 6. Specify Limits on Decision Errors**

Measurement of chemical concentration values in a biological sample is subject to error. Because of this error, two types of decision error are possible:

> Type I Error (False negative): The measured concentration is below a level of concern when the true concentration is above a level of concern
>
> Type II Error (False Positive): The measured concentration is above a level of concern when the true concentration is below the a level of concern

Both types of error are undesirable and should be limited to the extent possible. The most effective way to do this is ensure that measured concentration values have a high probability of being within a specified factor of the true value. These accuracy goals are specified below:

| Sample Type | Concentration Range | Data Quality Objectives |
|---|---|---|
| Blood lead | 0-15 ug/dL<br>> 15 ug/dL | ± 2 ug/dL<br>± 20% |
| Urinary Arsenic | 0-50 ug/L<br>> 50 ug/L | ± 5 ug/L<br>± 20% |
| Hair Arsenic | 0-1 ug/g<br>> 1 ug/g | ± 0.05 ug/g<br>± 20% |

Achievement of these accuracy goals will limit the frequency of both Type I and Type II errors, and will ensure that if a decision error is made, the magnitude and consequences of the decision error will not result in the occurrence of any significant health risk to the individual.

**Step 7. Optimize the Design for Obtaining Results**

Data quality indicators will be monitored during performance of the project, and refinements in recruiting, sample collection, and sample analysis may be implemented as required.

## B. MEASUREMENT/DATA ACQUISITION

Figure 1 and Figure 2 (see Attachment 1) are flowcharts that summarize the main steps in the collection, handling, and analysis of samples during the VBI70 CHP biomonitoring program for lead and arsenic. Details are presented below.

### B1. Sampling Design

A series of neighborhood-based testing clinics will be organized and conducted in each of the neighborhoods within the VBI70 area. Target neighborhoods include Elyria/Swansea, Clayton, Cole, Curtis Park, and southwest Globeville. A subcommittee consisting of community representatives, Denver Environmental Health (DEH) and Northeast Denver Housing Center (NDHC) will develop a list of potential sites for the community-based clinics. CDPHE will be responsible for final selection of clinic sites and for coordinating logistics and staffing for all clinics. Separate clinics will be offered in each distinct neighborhood within the VBI70 area over the course of the program. Once locations and testing dates have been determined, program outreach, recruitment, and advertising for the clinics will be coordinated through DEH with the assistance of community members and trained health workers.

Blood lead testing will be recommended for all young children ages 12 to 72 months old. Arsenic testing will be recommended for a subset of children whose behavior indicates they have the potential for arsenic exposure due to high soil contact behavior. Clinic staff will administer a short soil exposure questionnaire to the parent/legal guardian of each child brought to the clinic, to determine whether arsenic testing is recommended (see Attachment 2, Form 2). In addition,

arsenic testing will be recommended for any child who either resides or spends a significant part of their day at a property where arsenic concentrations in soil exceed a level of potential concern for a pica child (47 ppm), whether or not any other risk factors are identified. In cases where data on arsenic levels in soil are not available, soil sampling will be recommended, especially in cases where exposure to soil may be elevated. Access forms giving signed consent to EPA to sample soil at a family's residence, will be available at each testing clinic. Clinic staff will ensure that signed consent (see Attachment 3) is given for lead and/or arsenic testing prior to sample collection.

## B2. Sample Reporting and Follow-up Testing

### B2.1 Reporting of Lead Test Results

All lead test results will be reported by the analytical laboratory to DHH and CDPHE. DHH will provide contact information to NDHC for all children with a blood lead level over 5 ug/dL, if signed consent for data sharing was obtained from the parent/legal guardian. DHH will be responsible for reporting lead test results back to each individual tested, and will provide appropriate case management for all individuals with an elevated blood lead test, including coordination of follow-up testing in a timely manner. DHH will be responsible for ensuring the privacy and confidentiality of all personal data collected from participants in the lead testing portion of the biomonitoring program, and will ensure that individual data are not released to other agencies or individuals unless written informed consent has been granted by that individual or their parent or legal guardian.

### B2.2 Reporting of Arsenic Test Results

All arsenic test results will be reported to CDPHE. CDPHE will then be responsible for reporting arsenic test results back to each individual tested, and will provide appropriate case management for all individuals with an elevated urinary arsenic or hair arsenic test, including coordination of follow-up testing in a timely manner. CDPHE will be responsible for ensuring the privacy and confidentiality of all personal data collected from participants in the arsenic testing portion of the biomonitoring program, and will ensure that individual data are not released to other agencies or individuals unless written informed consent has been granted by that individual or their parent or legal guardian.

### B2.3 Confirmatory Sampling for Elevated Blood Lead

Whenever an individual is identified with a blood lead value above 10 ug/dL (as measured using the filter paper technique), an effort will be made to collect a venous blood sample for confirmatory analysis. This venous confirmatory sample is important because venous samples are less prone to potential contamination from external sources than capillary samples. In addition, even though blood lead values are relatively stable over time, concentrations do fluctuate and so a single sample may not reflect the true long-term average.

The venous blood sample will be drawn at a DHH clinic in the VBI70 area. In order to facilitate sample collection and processing, the DHH case manager assigned to the child will work with the parents/guardians to select a convenient DHH clinic and to set a time for sample collection. The case worker will provide the parents with a card that records the address of the clinic selected and the date and time of sample collection. The card will include a sample identification number that will identify the individual as being part of the VBI70 CHP program, to ensure that confirmatory results are received by the case worker and the result entered into the project database for that individual. The parent will be instructed to take the card to the clinic when the sample is drawn and present the card to the clinic staff. The clinic staff will collect the sample at no cost to the patient, and use the card as a "voucher" to be submitted for payment from funding provided by EPA.

The venous blood sample will be submitted by DHH for analysis by a qualified laboratory selected by DHH. The results of the analysis will be reported to the parents by the DHH case manager, and will also be reported by the laboratory to CDPHE. Based on the initial and the confirmatory sample results, the DHH case worker will determine what follow-on case management activities may be needed (e.g., education, environmental investigation, additional monitoring, clinical management), and arrange for those activities with the appropriate agencies.

B2.4 Confirmatory Testing for Elevated Arsenic

Whenever an individual is identified with a urinary arsenic test value above 20 ug/L, or 20 ug/g (creatinine-corrected test), an effort will be made to collect a repeat urine sample. Because arsenic levels in urine are transitory (half-life of arsenic in urine of approximately 72 hours or less), a repeat test will only reflect arsenic exposure over the past few days prior to the test and, therefore, cannot be considered confirmatory. However, this repeat test will be important as an indicator of whether arsenic exposure is still occurring.

The repeat urine sample may be collected at one of the on-going neighborhood-based clinic sites in the VBI70 area, or the family may be provided with instructions for in-home urine collection, based on the preference of the family. In order to facilitate sample collection and processing, the DCEED case manager assigned to the child will work with the parents/guardians to select a convenient location for sample collection, and will coordinate any necessary in-home sample collection container delivery and sample drop-off. The urine sample will be submitted by DCEED for total non-dietary arsenic analysis by CTQ laboratory per the protocol described in Attachment 4. The results of the analysis will be reported to the parents by the DCEED case manager, who will determine what follow-on case management activities may be needed (e.g., education, environmental investigation, additional monitoring, clinical management), and arrange for those activities with the appropriate agencies.

Whenever an individual is identified with a hair arsenic value above 0.2 ug/g, an effort will be made to collect a repeat hair sample for confirmatory analysis. Confirmatory hair testing will be

offered through one of the on-going neighborhood-based clinics or by in-home collection, based on the preference of the family.

The hair sample will be submitted by DCEED for total arsenic analysis (of the most recent 4 cm of growth) by CTQ laboratory per the protocol described in Attachment 4. The results of the analysis will be reported to the parents by the DCEED case manager, who will determine what follow-on case management activities may be needed (e.g., education, environmental investigation, additional monitoring, clinical management), and arrange for those activities with the appropriate agencies.

## B3. Sampling Methods Requirements

### B3.1 Blood Sampling

Blood samples for lead analysis will be collected according to the standard protocol currently used at all State lead surveillance testing clinics (fingerstick/filter paper method). In brief, collection sites are provided with a filter paper collection device, which incorporates filter paper into a 'matchbook' format (Collins and Puskas 2003). Providers are instructed to wash the patient's hands with soap and water and then scrub the fingertip with an alcohol prep pad and allow to air dry. The skin of the prepped finger is pierced with a lancet and the first drop of blood is wiped off with sterile gauze. Subsequent drops that form on the finger are then transferred to each of the circles on the card using a capillary tube. After allowing the spots to dry for 2 – 5 minutes, the collector is closed like a matchbook, placed in a plastic 'ziploc' bag and sent to the laboratory for testing.

Normally, a single sample will be collected from each child. However, duplicate samples should be collected occasionally (approximately 1 in 20), especially if blood flow is strong and the child is not distressed by the collection procedure.

### B3.2 Urine Sampling

Trained clinic staff will instruct the child's parent/guardian on how to collect a urine sample at the clinic site. If a child is unable to provide a urine sample, the family will be provided with a urine container, instructions for home collection, and information on sample drop-off/pick-up. The minimum sample volume is about 20 mL. Clinic staff will store all urine containers at the clinic in a refrigerator or a cooler with blue ice. Urine samples may be held at 4°C for up to a week (maximum) before shipment to the laboratory. In general, coolers will be packaged for 2-day FedEx shipping to the analytical laboratory at the end of each clinic.

Normally, a single sample will be collected from each child. However, duplicate samples should be collected occasionally (approximately 1 in 20), either by splitting a single large urine sample into two separate bottles, or else by collection in two different bottles.

B3.3 Hair Sampling

Hair samples are collected by cutting a patch of about 0.5 cm in diameter from the upper neck region, as close to the scalp as possible. The hair is attached with a staple to a cardboard sample collection card with a preprinted grid. Each hair sample is attached to the card so that the most recent growth (hair closest to the scalp) is attached to the beginning of the grid. Each sample collection card indicates the total length of the hair sample that is to analyzed (0-4 cm). Each sample collection card is sealed in a labeled plastic bag for shipment to the laboratory. Hair samples will be mailed to the laboratory on a weekly basis at a minimum.

Normally, a single sample will be collected from each child. However, duplicate samples should be collected occasionally (approximately 1 in 20), either by splitting a large hair sample into two, or else by collecting two separate samples (if the child and parent are willing).

In the case of hair sampling, an issue of potential importance is whether the hair should be washed prior to collection. If hair is not washed, dust adhering to the hair may influence the measurement, and the effect of this may be significant[1]. However, for the purposes of this program, no effort will be made to request that parents wash a child's hair before hair sampling. This is because the presence of arsenic-contaminated dust in hair is a valuable indicator of potential exposure, whether or not the child has actually ingested significant quantities of the contaminated dust. However, it is important to recognize that elevated arsenic values measured in unwashed hair may not necessarily indicate that ingestion exposure has occurred.

## B4. Sample Documentation, Handling And Custody Requirements

B4.1 Field Documentation

A detailed protocol for sample collection and sample labeling is provided as Attachment 4. A copy of this protocol will be provided to all clinic workers.

Clinic staff will be responsible for collecting all necessary information and informed consent forms from study participants, using the forms and questionnaires (English and Spanish) developed specifically for this project (see Attachments 2 and 3). The clinic staff must ensure that all information that is recorded is accurate and legible, and that all case numbers and sample numbers are correctly assigned and recorded.

In brief, each child that participates in the program will be identified with a unique VBI70 CHP case number of the following format:

VBI70 CHP xxxx

[1] For example, consider a hair sample whose true arsenic content is 1.0 ug/g. If the hair sample contains 1% by mass of adhering dust and the concentration of arsenic in the dust is 100 ug/g, the amount of arsenic contributed by the adhering dust will be equal to the amount of arsenic in the hair.

All samples provided by that child will also be assigned the same unique identification number. These numbers will be provided as pre-printed sheets of self-adhesive labels that will be available in each sample collection facility. Each sheet will contain multiple copies of each number.

B4.2 Sample Handling, Chain of Custody, and Sample Shipment

*Chain of Custody and Shipping Transmittal Memo*

All samples collected will be maintained under standard chain-of-custody procedures. A chain-of-custody form shall accompany every shipment of samples to the analytical laboratory (see Attachment 2, Forms 4 and 5). The purpose of the chain-of-custody form is to establish the documentation necessary to trace possession from the time of collection to final disposal, and to identify the type of analysis requested. All corrections to the chain-of-custody record will be initialed and dated by the person making the corrections. Each chain-of-custody form will include signatures of the appropriate individuals indicated on the form. The originals will accompany the samples to the laboratory, and copies documenting each custody change will be recorded and kept on file.

All required paper work, including sample container labels, chain-of-custody forms, custody seals and shipping forms will be fully completed in ink (or printed from a computer) prior to shipping of the samples to the laboratory. The shipping forms or transmittal memo will describe:

- Number of samples
- Date and time of sample shipment
- Analyses requested

*Sample Shipping*

Blood

Blood samples on filter paper will be delivered by CDPHE to a Denver Health and Hospital (DHH) Lab on a daily basis. Contact information is provided below:

Ingrid Canon
Project Coordinator
Denver Health and Hospital Laboratory
Phone: 303-436-6937

Filter paper samples may be transferred or shipped at ambient temperature.

Urine

Samples of urine will be shipped to CTQ in Quebec, Canada. Contact information is provided below:

Laboratoire de toxicologie / INSPQ
945, avenue Wolfe, 4ème étage
Sainte-Foy, Quebec
Canada G1V 5B3
Phone : (418) 654-2100
Email : ctqlab@inspq.qc.ca

Shipments will be packaged in coolers with blue ice for shipping at the end of each clinic session, or stored and shipped in bulk weekly, depending on the number of clinics scheduled and number of samples collected each week. Each shipment will include a chain-of-custody form that lists all samples in the shipment and identifies the analysis requested.

Hair

Samples of hair will also be shipped to CTQ at the address listed above. Shipments will occur weekly, or more often if needed. Shipment of hair may be at ambient temperature. Each shipment will include a chain-of-custody form that lists all samples in the shipment and identifies the analysis requested.

B4.3 Record Keeping

All sample information forms and all chain-of-custody forms will be maintained until final disposition of the samples by the laboratory and acceptance of analytical results by the project team.

## B5. Analytical Methods Requirements

Blood Samples (Filter Paper)

For the analysis of lead in filter-paper blood samples, two 3/16" punches of each sample are punched directly into 15 ml disposable tubes. Blanks are punched in-between each sample to control for carryover. Tubes are vortexed after addition of bismuth internal standard and 3 mL 0.5% nitric acid, allowed to sit for 10 minutes, and vortexed again for 1 minute. Prepped samples are then placed on the autosampler and analyzed by ICP-MS. Analytical conditions are optimized for each instrument model.

Quantification is achieved by generation of a standard curve with each analytical batch. The typical detection limit is 1 ug/dL. Any samples with elevated results (≥10 ug/dL) are repeated on a subsequent batch prior to reporting the result. This 're-verification' includes analysis of a filter paper blank prepared from the patient's collection card and resampling of the collected capillary blood. Filter paper blanks that exceed 1 ug/dL lead concentration are not considered reliable and a recollection of a blood sample will be requested. Results that meet required reproducibility criteria will be reported in accordance with CDC guidelines.

Urine Samples

All samples of urine will be analyzed for total non-dietary arsenic. This total includes both trivalent and pentavalent forms of inorganic arsenic ($As^{+3}$, $As^{+5}$), as well as the primary urinary metabolites of these forms (monomethyarsonate (MMA), and dimethylarsinate (DMA)). Complex organic arsenicals found in seafood (e.g., arsenobetaine) are not included in the total.

Details of the sample preparation and analysis are proprietary. In general, iodine is added to the sample and the target analytes are extracted into an organic phase under acidic conditions. A portion of this extract is analyzed for arsenic via ICP-MS. The detection limit is approximately 1.0 ug/L.

Hair Samples

All samples of hair will be analyzed for total arsenic, using the first 4 cm (representing approximately the last two months of growth) of the hair sample attached to the collection card. In brief, the hair sample is weighed, digested in hot nitric acid, and analyzed by ICP-MS. The hair is not washed before digestion. The typical detection limit is about 0.01 ug/g.

## B6. Quality Control Requirements

*Laboratory-Based QC Samples*

A series of different types of quality control (QC) tests are routinely performed within each analytical laboratory for each analytical method to evaluate the accuracy and precision of test results and to identify any analyses that fall outside acceptable limits. These laboratory-based QC samples include various blanks, duplicates, spikes, and laboratory control standards (see Attachment 6). All routine internal laboratory QC results will be obtained and evaluated as part of the data quality evaluation process for this effort.

*Field-Based QC Samples*

In addition to the laboratory-based QC samples, a series of field-based QC samples will be included to provide further evaluation of data accuracy and precision. These are described below.

Field Split: Field split samples are two aliquots of the same sample. These samples are submitted blind to the laboratory to measure the precision of laboratory analysis. As described above, field splits will be collected at a frequency of about 5% for blood, urine, and hair, on an opportunistic basis.

The acceptance criterion for field split samples depends on how close the value is to the practical quantitation limit (PQL). For samples more than 5-times the PQL, the initial acceptance criterion is a Relative Percent Difference (RPD) of no more than 30%. For samples less than 5-times the PQL, the initial acceptance criterion is an absolute difference of no more than one-times the PQL. These acceptance criteria may be revised as data become available during the project.

Performance Evaluation (PE) samples are samples of a medium that contain a known and certified level of a contaminant. These samples are submitted blind to the laboratory to measure both the accuracy and the precision of laboratory analysis. PE samples for each medium will be submitted at an overall frequency of about 5%.

The PE samples that will be used in this program are described below. All PE samples will be collected and submitted by the field staff according to the protocol described in Attachment 5.

*Blood PE Samples*
Blood PE samples will be obtained from CDC's blood lead proficiency testing program. A set of three different concentration values will be used:

| | |
|---|---|
| Low | = < 1 ug/dL |
| Medium | = 3-8 ug/dL |
| High | = 12-20 ug/dL. |

The exact concentration value will depend on sample availability at CDC, and may change during the course of the program.

*Urine PE Samples.*
Urine PE samples will be purchased from CTQ in Quebec. Preference will be given to urine samples from human volunteers in order to ensure that the samples contain a mixture of arsenic species. A set of three different concentration values will be used:

| | |
|---|---|
| Low | = < 20 ug/L |
| Medium | = 20-100 ug/L |
| High | = 100-300 ug/L. |

The exact concentration values will depend of sample availability at CTQ, and may change during the course of the program.

*Hair PE Samples.*
At present, no suitable PE samples for hair are available.

Initial acceptance criteria for each type of PE sample will be the value recommended by the supplier. These acceptance criteria may be revised as data become available during the program.

## B7. Instrument/Equipment Testing, Inspection And Maintenance Requirements

Sample Collection Equipment

All sample collection equipment (blood filter paper kits, lancets, urine bottles, etc) will be maintained in a way that prevents contamination.

Laboratory Equipment

All laboratory instruments used in the analysis of samples generated during this project must be calibrated by the laboratory in accord with the requirements of the instrument manufacturer and the requirements specified in the relevant analytical method. Laboratory instrumentation used for sample analyses will be calibrated in accordance with the recommended analytical methodologies. Calibrations must be acceptable before any measurements on investigative samples may be made. Certified reference materials (CRM) will be obtained by the analytical laboratories. All documentation relating to receipt, preparation and use of CRM will be documented and reported in a quality control chart, to be forwarded as part of the raw analytical data package.

## B8. Data Management

All data will be entered into a project-specific database by appropriately trained data entry staff. The data entered into the database will include all relevant field information regarding each environmental sample collected, as well as the analytical results provided by the laboratory. All data entries will be reviewed and validated for accuracy by the data entry manager or his/her delegate. All original data records (both hard copy and electronic) will be cataloged and stored in their original form until otherwise directed by the project directors.

# SECTION C. ASSESSMENT AND OVERSIGHT

The following sections describe activities for assessing the effectiveness of the implementation of the project and associated QA/QC. The purpose of the assessment is to ensure that the project plan is implemented as prescribed. The elements include assessments and response actions and reports to management as described in the following sections.

## C1. Assessment And Response Actions

Quality Assurance (QA) assessments performed during this project will include the following:

1) Oversight of sample collection activities
2) Review and oversight of laboratory procedures through QC sample verification

Sampling Activities Oversight

Assessment of sample collection activities will be conducted by a representative of CDPHE or USEPA. Oversight of field activities will consist of unannounced visits to a collection center in order to observe sample collection procedures.

At least one assessment will occur for each collection center, and additional assessments at a center may occur if issues or problems are detected. Any appropriate response action(s) that may be deemed necessary to resolve problems detected during the assessments should be identified during oversight activities. This could range from a simple review of approved SOPs with sample collection staff to address minor problems up to a temporary cessation of sample collection to provide time for senior project managers to address more significant issues.

Laboratory Procedure Oversight

The quality of laboratory analyses will be assessed by evaluation of field and laboratory QC samples (see Section B5). Any deviation of a QC sample from the acceptance criteria above will be evaluated and a corrective action selected. If deviations are minor (only slightly outside the acceptance bounds) and are not consistent over time or sample type, no action will be required. If deviations are consistent (occurring in two or more consecutive weeks) or if deviations are not trivial, the laboratory will be contacted to discuss possible causes and appropriate laboratory corrective actions.

## C2. Reports To Management

The representatives of CHDPE or EPA who provide oversight of the implementation of the QAPP will provide the biomonitoring steering committee with verbal reports on project status, as needed. These reports will cover sampling and analysis progress and data quality assessment issues, and will identify any significant problems and recommended solutions.

# SECTION D. DATA VALIDATION AND USABILITY

## D1. Data Review, Verification, And Validation

The process of data review, validation and verification is intended to provide consistent and defensible analytical results. Analytical data generated as part of this project will be reviewed

and verified before they are incorporated into the project database. Methods for verification and validation are described below.

## D2. Verification And Validation Methods

### D2.1 Data Verification

Data verification will include a review of the findings of all QA assessment activities (see Section C), including assessments of sample collection procedures, sample labeling methods, chain-of-custody procedures, and all assessments of analytical data collection, recording and reporting. If any deviations are identified, the potential impact of those deviations on the reliability of the data will be assessed, and that information will be provided to the biomonitoring steering committee.

### D2.2 Data Validation

The data validation process consists of a detailed evaluation of laboratory QC data to ensure that results are within acceptable limits. The following elements, when applicable, will be reviewed for compliance during data validation:

- Was the specified method used to analyze the sample?
- Was the sample analyzed within the required holding time?
- Was the instrument properly calibrated before analysis?
- Were laboratory blanks free of contamination?
- Were laboratory spike recoveries within acceptance criteria?
- Were laboratory duplicates within acceptance criteria?
- Were LCS results within specified acceptance criteria?
- Was the detection limit adequate?

## D3. Reconciliation With DQOs

Data obtained during the VBI70 CHP biomonitoring program will be periodically evaluated through the Data Quality Assessment (DQA) process (USEPA 1996, 1998) to determine if the data obtained are of adequate quality and quantity to support their intended use. Steps in the DQA process that are applicable to this project are summarized below.

Review the DQOs and Sampling Design: DQO outputs will be periodically reviewed to ensure that they are still applicable. The sampling analysis and data collection procedures will also be reviewed to ensure they are effective and appropriate.

Conduct a Preliminary Data Review: Data validation reports will be reviewed to identify any significant limitations associated with the analytical data. Basic summary statistics will be calculated to learn about the structure of the data and to help identify temporal or

spatial patterns, and to help identify any potential anomalies/outliers.

Select the Statistical Test: Although the primary objective of the biomonitoring program does not involve any statistical tests, the secondary objective calls for investigating the strength of correlation between soil and exposure levels. This will be done using simple correlation and regression analysis.

## SECTION E. REFERENCES

Collins JA, Puskas SE. 2003. Experience Using Filter Paper Techniques for Whole Blood Lead Screening in a Large Pediatric Population. MEDTOX Laboratories, Inc., Saint Paul, MN.

USEPA. 1994. USEPA Requirements for Quality Assurance Project Plans for Environmental Data Operations. Draft Interim Final. U.S. Environmental Protection Agency, Quality Assurance Management Staff. USEPA QA/R-5.

USEPA. 1996. Quality Management Plan for the U.S. Environmental Protection Agency, Region 8. Version 1.0. Denver, CO.

USEPA. 1998. USEPA Requirements for Quality Assurance Project Plans for Environmental Data Operations. Draft Interim Final. U.S. Environmental Protection Agency, Quality Assurance Management Staff. USEPA QA/R-5.

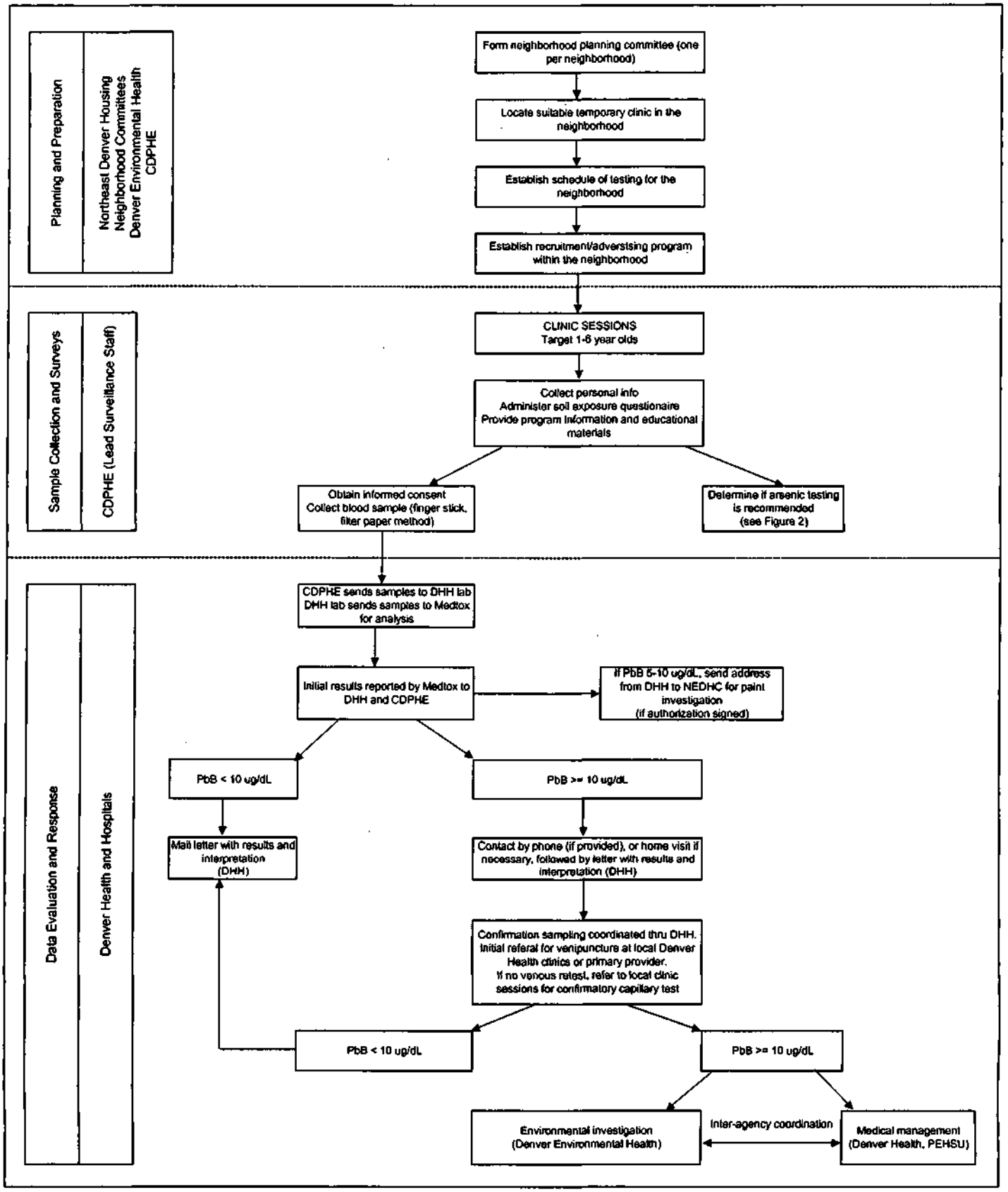
USEPA. 2000. Guidance for the Data Quality Objectives Process (QA/G-4). Final. U.S. Environmental Protection Agency, Quality Assurance Management Staff. EPA/600/R-96/055.

USEPA. 2002. Guidance for Quality Assurance Project Plans (QA/G-5). Final. U.S. Environmental Protection Agency, Quality Assurance Management Staff. EPA/600/R-00/007.

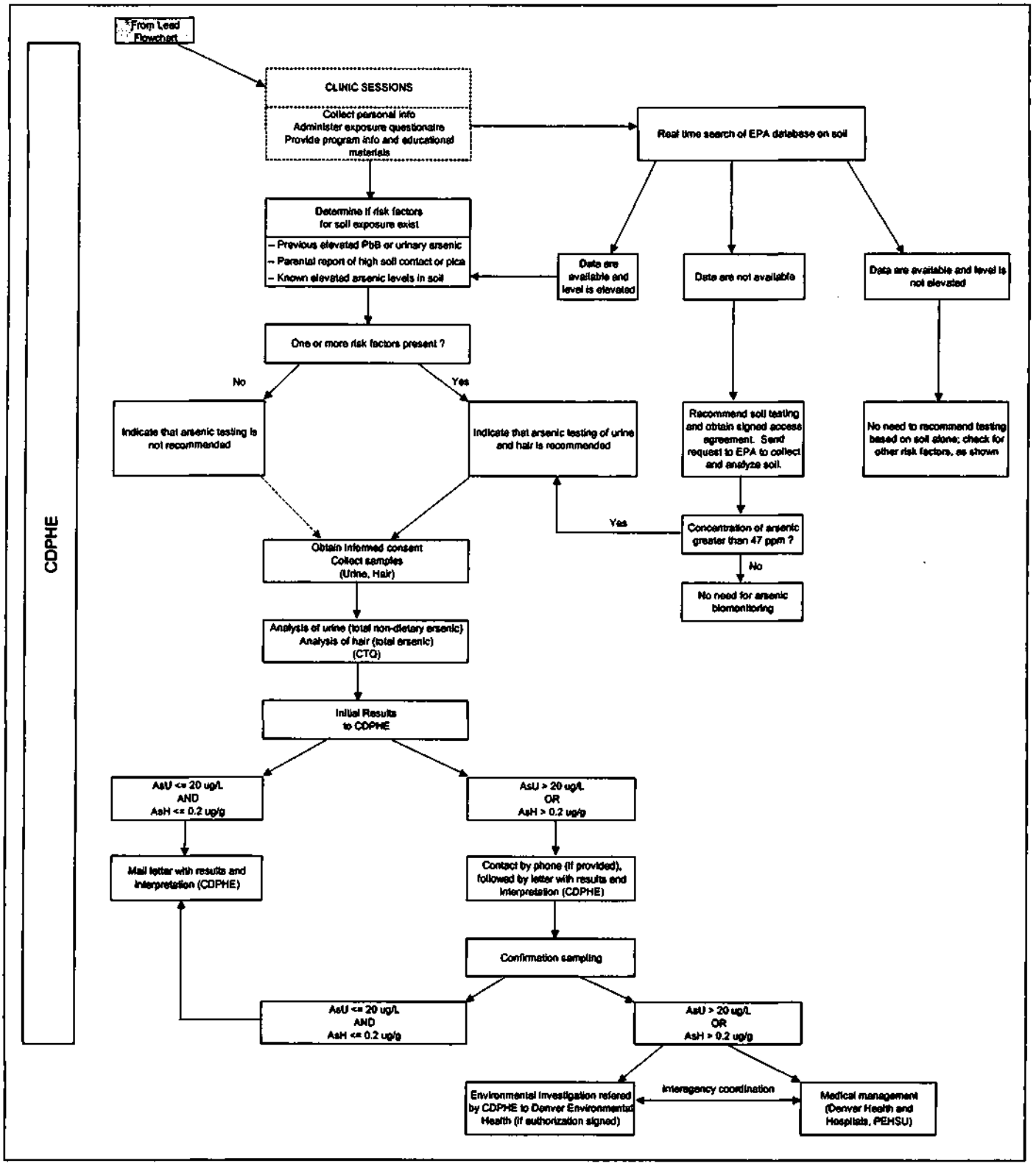
# Attachment 1

# Flowcharts for Lead and Arsenic Exposure Evaluation

## FIGURE 1. FLOW CHART FOR LEAD EXPOSURE EVALUATION



## FIGURE 2. FLOW CHART FOR ARSENIC EXPOSURE EVALUATION



# Attachment 2

# Data Collection and Tracking Forms

## FORM 1: GENERAL INFORMATION

Interviewer Initials: _____ TEST SITE:

Interview Language (circle): English / Spanish Date of Interview: ___/___/_____

Name of Adult: _____ _____
First Last

Address: _____ _____
Street Name and No. ZIP

Neighborhood (circle one): Cole Clayton Elyria Swansea SW Globe Curtis Park

How long have you lived at your current address? Years _____ Months _____

Have you lived at another address within the VB70 area in past 6 months? YES ___ NO ____

If yes, previous address: _____ _____
Street Name and No. ZIP

How long at previous address? Years _____ Months _____

| CHILD INFORMATION | Child 1 | Child 2 | Child 3 |
|---|---|---|---|
| First Name | | | |
| Last Name (if different than adult) | | | |
| Date of Birth (dd/mm/yyyy) | | | |
| Gender (enter M or F) | | | |
| Race (enter one letter)<br>B=Black W=White M=Multi-racial<br>A=Asian/Pacific Islander<br>N=Native American, Eskimo, Aleutian<br>O=Other U=Unknown | | | |
| Ethnicity (enter one letter)<br>H=Hispanic N=Non-Hispanic<br>O=Other U=Unknown | | | |
| Does your child currently receive Medicaid benefits? (Yes/No) | | | |
| Does child attend daycare or school? If yes, enter name of facility | | | |
| Case Number | *Place label here* | *Place label here* | *Place label here* |

| CHILD INFORMATION | Child 4 | Child 5 | Child 6 |
|---|---|---|---|
| First Name | | | |
| Last Name (if different than adult) | | | |
| Date of Birth (dd/mm/yyyy) | | | |
| Gender (enter M or F) | | | |
| Race (enter one letter)<br>B=Black W=White M=Multi-racial<br>A=Asian/Pacific Islander<br>N=Native American, Eskimo, Aleutian<br>O=Other U=Unknown | | | |
| Ethnicity (enter one letter)<br>H=Hispanic N=Non-Hispanic<br>O=Other U=Unknown | | | |
| Does your child currently receive Medicaid benefits? (Yes/No) | | | |
| Does child attend daycare or school?<br>If yes, enter name of facility | | | |
| Case Number | *Place label here* | *Place label here* | *Place label here* |

## FORM 2: ARSENIC QUESTIONAIRE

Child name:

_____

Place ID Label Here

Arsenic concentration at current residence
(*from EPA database*): _____ ppm

Check here if no data: _____

## PART A: SOIL ARSENIC EVALUATION

1a. Is there another location in VB70 where your child spends four hours per day or more, at least 3 days per week? | YES | NO |

If yes, what is the address? _____

1b. Enter arsenic concentration (*from EPA database*) _____ ppm ____ No data

2. Has your child ever had an elevated blood lead test? (If no, skip to Question 3) | YES | NO | Don't Know |

2a. Did a doctor, nurse, or other health worker tell you your child had a high level of lead in their blood? | YES | NO | Don't Know |

2b. Please provide contact information if we may contact them:

_____

3. Has a doctor, nurse, or other health worker ever told you your child had a high level of arsenic in their urine? | YES | NO | Don't Know |

4. Has your child ever eaten dirt in the past 6 months? | YES | NO | Don't Know |

5. Has your child eaten dirt in the past 2 weeks? | YES | NO | Don't Know |

6. Is it typical for your child to eat dirt most weeks? | YES | NO | Don't Know |

IF FAMILY ANSWERS "YES" TO ANY OF QUESTIONS 2-6, OR IF SOIL LEVEL >47 ppm, RECOMMEND ARSENIC TESTING AND PROCEED TO PART B QUESTIONS BELOW.

IF FAMILY ANSWERS "NO" TO ALL QUESTIONS, **AND** SOIL LEVELS ≤47, OR SOIL NOT SAMPLED, RECOMMEND LEAD TESTING ONLY. SKIP PART B.

## PART B. ARSENIC EXPOSURE QUESTIONS

*Note: The Part B questions should be **asked only if** arsenic testing has been recommended.*

---

1. Has your child eaten any of the following fish or other seafood within the past 3 days?

| | | |
|---|---|---|
| Canned tuna? | Salmon? | Shrimp? |
| Oysters? | Crab? | Clams? |
| Sardines? | Other fish? | |

| YES | NO | Don't Know |
|---|---|---|

2. Has your child played outdoors in your yard in bare soil within the past 3 days?

| YES | NO | Don't Know |
|---|---|---|

3. Within the past six months, has your child used any hair treatments such as hair color or dyes, permanents, hair straighteners, or other chemical treatments?

| YES | NO | Don't Know |
|---|---|---|

# VBI70 COMMUNITY HEALTH PROGRAM
# FORM 3: SAMPLES COLLECTED

Child name: _____

Case Number: *Place VBI70 CHP label here*

***If sample is PE, list description here:***

ID Number (CTQ or CDC): _____ Nominal Value _____

---

***If samples are authentic, fill in below (circle):***

| | | |
|---|---|---|
| **Blood lead** | Recommended? | YES |
| | Consent Form Signed? | YES NO |
| | Samples collected | 0 1 2 |
| | Sample label from MedTox | |
| | Sample label from MedTox (if duplicate collected) | |
| **Urinary arsenic** | Recommended? | YES NO |
| | Consent Form Signed? | YES NO |
| | Samples collected | 0 1 2 |
| | Date collected | ____/____/_____ |
| | Location collected | HOME CLINIC |
| **Hair arsenic** | Recommended? | YES NO |
| | Consent Form Signed? | YES NO |
| | Samples collected | 0 1 2 |

Notes or comments:

# VBI70 COMMUNITY HEALTH PROGRAM
## FORM 4: CHAIN OF CUSTODY FOR URINE SAMPLES

Prepared by: Sample Date: ____/____/_____

| Index | Sample Number | | Medium | Analysis Requested | Notes |
|---|---|---|---|---|---|
| 1 | VBI70 CHP | | Urine | Total non-dietary arsenic | |
| 2 | VBI70 CHP | | Urine | Total non-dietary arsenic | |
| 3 | VBI70 CHP | | Urine | Total non-dietary arsenic | |
| 4 | VBI70 CHP | | Urine | Total non-dietary arsenic | |
| 5 | VBI70 CHP | | Urine | Total non-dietary arsenic | |
| 6 | VBI70 CHP | | Urine | Total non-dietary arsenic | |
| 7 | VBI70 CHP | | Urine | Total non-dietary arsenic | |
| 8 | VBI70 CHP | | Urine | Total non-dietary arsenic | |
| 9 | VBI70 CHP | | Urine | Total non-dietary arsenic | |
| 10 | VBI70 CHP | | Urine | Total non-dietary arsenic | |
| 11 | VBI70 CHP | | Urine | Total non-dietary arsenic | |
| 12 | VBI70 CHP | | Urine | Total non-dietary arsenic | |
| 13 | VBI70 CHP | | Urine | Total non-dietary arsenic | |
| 14 | VBI70 CHP | | Urine | Total non-dietary arsenic | |
| 15 | VBI70 CHP | | Urine | Total non-dietary arsenic | |
| 16 | VBI70 CHP | | Urine | Total non-dietary arsenic | |
| 17 | VBI70 CHP | | Urine | Total non-dietary arsenic | |
| 18 | VBI70 CHP | | Urine | Total non-dietary arsenic | |
| 19 | VBI70 CHP | | Urine | Total non-dietary arsenic | |
| 20 | VBI70 CHP | | Urine | Total non-dietary arsenic | |

| | | |
|---|---|---|
| **Custody Transfer Record No. 1** | | |
| Custody relinquished by | Name | Date ___/___/___ |
| Custody accepted by | Name | Date ___/___/___ |
| **Custody Transfer Record No. 2** | | |
| Custody relinquished by | Name | Date ___/___/___ |
| Custody accepted by | Name | Date ___/___/___ |


**SEND SAMPLE RESULTS TO:**
**Jane Mitchell**
**CDPHE - DCEED-EE-A3**
**4300 Cherry Creek Drive South**
Denver, CO. 80246-1530 USA
303-692-2644
jane.mitchell@state.co.us

# VBI70 COMMUNITY HEALTH PROGRAM

## FORM 5: CHAIN OF CUSTODY FOR HAIR SAMPLES

Prepared by: Sample Date: ____/____/_____

| Index | Sample Number | Medium | Analysis Requested | Notes |
|---|---|---|---|---|
| 1 | VBI70 CHP | Hair | Total arsenic | |
| 2 | VBI70 CHP | Hair | Total arsenic | |
| 3 | VBI70 CHP | Hair | Total arsenic | |
| 4 | VBI70 CHP | Hair | Total arsenic | |
| 5 | VBI70 CHP | Hair | Total arsenic | |
| 6 | VBI70 CHP | Hair | Total arsenic | |
| 7 | VBI70 CHP | Hair | Total arsenic | |
| 8 | VBI70 CHP | Hair | Total arsenic | |
| 9 | VBI70 CHP | Hair | Total arsenic | |
| 10 | VBI70 CHP | Hair | Total arsenic | |
| 11 | VBI70 CHP | Hair | Total arsenic | |
| 12 | VBI70 CHP | Hair | Total arsenic | |
| 13 | VBI70 CHP | Hair | Total arsenic | |
| 14 | VBI70 CHP | Hair | Total arsenic | |
| 15 | VBI70 CHP | Hair | Total arsenic | |
| 16 | VBI70 CHP | Hair | Total arsenic | |
| 17 | VBI70 CHP | Hair | Total arsenic | |
| 18 | VBI70 CHP | Hair | Total arsenic | |
| 19 | VBI70 CHP | Hair | Total arsenic | |
| 20 | VBI70 CHP | Hair | Total arsenic | |

| | | |
|---|---|---|
| **Custody Transfer Record No. 1** | | |
| Custody relinquished by | Name | Date ___/___/___ |
| Custody accepted by | Name | Date ___/___/___ |
| **Custody Transfer Record No. 2** | | |
| Custody relinquished by | Name | Date ___/___/___ |
| Custody accepted by | Name | Date ___/___/___ |

**SEND SAMPLE RESULTS TO:**

**Jane Mitchell**
**CDPHE - DCEED-EE-A3**
**4300 Cherry Creek Drive South**
Denver, CO. 80246-1530 USA
303-692-2644
Jane.mitchell@state.co.us

Attachment 3

Informed Consent

Colorado Department of Public Health and Environment

# VB/I70 Community Health Program Consent Form for Blood Lead Testing DHHA ID# _____

DENVER HEALTH

As part of the VB/ I-70 Community Health Program, we are offering free blood tests for lead to all children one to six years old that live in the VB/I70 Superfund site. Lead poisoning hurts children by causing problems with their development and ability to learn.

We will collect a few drops of your child's blood by pricking their finger with a lancet. Your child may feel some discomfort when the lancet pricks the finger. Trained health care workers will collect the blood sample.

We will only test the blood sample to measure lead. We will send the result of your child's blood test to you through the mail. This may take two weeks. If we find your child has too much lead in their blood, the Denver Health Lead Coordinator will contact you to help you get additional testing and medical treatment for your child. You may also be referred for additional free services if they are needed. These may include a home investigation by Denver Environmental Health, and removal of lead by Northeast Denver Housing Center and the U.S. Environmental Protection Agency (EPA).

All information will be kept confidential. Your name, address, your child's name and other identifying information will **NOT** be used in any published report or given to any other person other than you and your state or local health department.

AUTHORIZATION TO HAVE A LEAD TEST: I have read the information above and understand the possible discomforts and inconveniences of having my child's blood drawn. I agree to the participation of:

**CHILD'S NAME** _____ **BIRTHDATE** _____ ***(Result*** _____***)***

***Site*** _____

**ADDRESS** _____ **CITY** _____ **ZIP** _____

**HOW LONG HAVE YOU LIVED AT THIS ADDRESS?** _____ **YRS** _____ **MONTHS**

**PHONE (** _____**)** _____ **PARENT NAME (print)** _____

**EMERGENCY CONTACT** _____ **EMERG. PHONE (** _____**)** _____

**CHILD'S PRIMARY CARE PROVIDER OR CLINIC** _____

**SIGNATURE** _____ **DATE** _____

Adult parent or guardian

AUTHORIZATION TO SHARE INFORMATION: If your child has a high blood lead level and you qualify for additional free services, other agencies may want to contact you.

*By signing below, I give permission to the Lead Poisoning Prevention Team (Including Denver Health and Hospitals, Denver Environmental Health, Northeast Denver Housing Center, the State Health Department and the EPA) to share information about my child's blood lead level and address. By sharing this information, I understand I am permitting a representative of these agencies to contact me about free follow-up services. I understand that participation in this screening is voluntary, and that if I refuse to sign here I will not lose benefits or medical care to which I am otherwise eligible, and my child can still get a free blood lead test. This permission will remain in place for one year unless I withdraw it.*

**SIGNATURE** _____ **DATE** _____

Adult parent or guardian

If you have questions about lead poisoning, please call Mishelle Macías, State Health Department, 303-692-2622, or Keira Zapien, Denver Health and Hospitals, 303-436-3764, to find out your test results.

Colorado Department of Public Health and Environment

**Programa Comunitario de Salud VB/I70 - Consentimiento para hacer pruebas en la sangre**

**DHHA ID# _____**

DENVER HEALTH

Como parte del Programa Comunitario de Salud VB/ I-70 C, estamos ofreciendo pruebas gratuitas para detectar plomo en la sangre, para todos los niños de uno a seis años de edad, que vivan en el sitio Superfund VB/I70. El envenenamiento con plomo daña a los niños causándoles problemas en su desarrollo y habilidad para aprender.

Vamos a recoger unas gotas de sangre de su hijo picándole un dedo con la punta de un bisturí. Su hijo puede sentir alguna molestia al pincharle el dedo. Trabajadores capacitados de salubridad recogerán la muestra de sangre.

Hacemos la prueba en la sangre sólo para detectar plomo. Le mandaremos por correo el resultado del análisis de la sangre de su hijo(a). Esto puede tardar dos semanas. Si encontramos que su hijo tiene demasiado plomo en la sangre, el Coordinador de Denver Health Lead se pondrá en contacto con usted para ayudarle a tener más pruebas y tratamiento médico para su hijo. También se le puede canalizar para que reciba servicios adicionales gratuitos si se necesitan. Esto puede incluir una investigación que haga de su casa de la Oficina de Salud Ambiental de Denver, o que el Centro para la Vivienda del Noreste de Denver y la Agencia de Protección Ambiental (EPA) remuevan el plomo.

Toda la información se mantendrá confidencial. Su nombre, dirección, el nombre de su hijo y otra información de identificación **NO SE USARÁN** en ningún reporte que se publique ni se dará a ninguna persona que no sea usted y su departamento de salud local o estatal, sin su permiso por escrito.

**AUTORIZACIÓN PARA HACER LA PRUEBA DEL PLOMO**: He leído la información que antecede y entiendo los posibles molestias e inconveniencias de hacer que a mi hijo se le saque sangre. Estoy de acuerdo en la participación de:

**NOMBRE DEL NIÑO** _____ **FECHA DE NACIMIENTO** _____ [redacted]

*Lugar* _____

**DOMICILIO**_____ **CIUDAD** _____ **ZIP** _____

**TELEFONO** (____)____-_____ **NOMBRE DEL PADRE/MADRE (letra de imprenta)** _____

**CONTACTO DE EMERGENCIA** _____ **TELÉFONO DE EMERGENCIA** (____)____-_____

**PROVEEDOR O CLINICA PARA LA ATENCION MEDICA DEL NIÑO** _____

**FIRMA**_____ **FECHA**_____

Padre/madre o tutor adulto

**AUTORIZACIÓN PARA COMPARTIR LA INFORMACIÓN CON OTRAS DEPENDENCIAS DE SALUD:**: Si su hijo tiene un nivel alto de plomo en la sangre y usted califica para recibir servicios gratuitos adicionales, otras agencias pueden necesitar comunicarse con usted.

*Al firmar abajo, doy permiso al Lead Poisoning Prevention Team (incluyendo Denver Health and Hospitals, Denver Environmental Health, Northeast Denver Housing Center, el Departamento de Salud del Estado y EPA) para que comparta la información sobre los niveles de plomo de mi hijo y su dirección. Al compartir esta información, entiendo que estoy permitiendo que un representante de estas agencias se ponga en contacto conmigo en relación con estos servicios gratuitos de seguimiento. Entiendo que la participación en este programa de pruebas es voluntaria, y que si decido no firmar abajo, no perderé los beneficios o la atención médica a los que tengo derecho por otro concepto, y que a mi hijo de le harán las pruebas gratuitas del plomo. Este permiso se mantendrá vigente durante un año a menos de que yo lo revoque.*

**FIRMA**_____ **FECHA** _____

Padre/madre o tutor adulto

Si usted quiere hacer alguna pregunta acerca del envenenamiento por plomo, llame a Mishelle Macías, del Departamento de Salud del Estado, al 303-692-2622, o a Keyra Zapién, al Denver Health and Hospitals, al 720-956-2151, para saber sus resultados.

Colorado Department of Public Health and Environment

Place participant Id label here

# Vasquez Boulevard/I70 Community Health Program
# Consent Form for Arsenic Testing

As part of the VB/I70 Community Health Program, we are offering free arsenic testing to young children, ages one to six years old, who live within the VB/I-70 Superfund Site. The Health Department recommends that you have your child's urine and hair tested for arsenic if you live at a home with high levels of arsenic in your soil, or if your answers to the short soil risk questionnaire indicate your child may be at increased risk of exposure to arsenic in your yard soil. Exposure to high levels of arsenic has been linked to a number of health risks, including digestive tract problems and skin abnormalities (e.g., discoloration and unusual growths which may become cancerous).

Trained health care workers will collect a hair sample from your child and give you instructions about how to help your child provide a urine specimen. If your child is not able to provide a urine sample at the test site, we will give you instructions for collecting a sample at your home, and tell you how to store the sample until you deliver the sample to a neighborhood collection site. For the hair test, a small piece of hair (about the thickness of a pencil) will be cut from the back of the head at the nape of the neck, where it is least visible.

We will only test the urine and hair samples for arsenic. A health coordinator will send the results of your child's test to you through the mail. It may take about three weeks to receive your child's test results. If we find your child has too much arsenic in their urine or hair, a health coordinator from the state Health Department will contact you. You may be asked to have your child retested or be referred for additional free services, if they are needed and you give your consent. This may include a home investigation from Denver Environmental Health, or removal of arsenic from your yard by the Environmental Protection Agency (EPA).

All information you provide will be kept confidential. Your name, address, your child's name and other personal information will **NOT** be used in any published report or given to any person other than you and your state or local health department, without your written permission.

---

**AUTHORIZATION FOR ARSENIC TESTING**: *I have read the information above and understand the possible inconveniences of having my child provide a urine and hair sample. I agree to the participation of:*

**CHILD'S NAME** _____ **BIRTHDATE** _____ **TEST SITE** _____

**ADDRESS** _____ **CITY** _____ **ZIP** _____

**PHONE** (_____)_____-_____ **PARENT's NAME (print)** _____

**EMERGENCY CONTACT** _____ **EMERG. PHONE** (____)____-_____

**CHILD'S PRIMARY CARE PROVIDER OR CLINIC** _____

**SIGNATURE** _____ **DATE** _____

Adult parent or guardian

---

**AUTHORIZATION TO SHARE INFORMATION WITH OTHER HEALTH AGENCIES:** If your child has a high arsenic level and you qualify for additional free services, other agencies may need to contact you about these services. Information will only be shared with the appropriate agency that is able to provide additional follow-up for you and your family.

*By signing below, I give permission to the Arsenic Exposure Investigation Team (including the State Health Department, Denver Health and Hospitals, Denver Environmental Health, and EPA) to share information about my child's arsenic levels and address. By sharing this information, I understand I am permitting a representative of these agencies to contact me about free follow-up services. This permission will remain in place for one year unless I withdraw it. I understand that participation in this testing program is voluntary, and that if I refuse to sign below I will not lose benefits or medical care to which I am otherwise eligible, and my child may still get free arsenic tests as long as I have signed the "AUTHORIZATION FOR ARSENIC TESTING" in the previous section.*

**SIGNATURE** _____ **DATE** _____

Adult parent or guardian

If you have questions about arsenic testing, call Jane Mitchell, at the Colorado Department of Public Health and Environment, at 303-692-2644.

Colorado Department of Public Health and Environment

Place participant Id label here

# Vasquez Boulevard/I70 Programa Comunitario de Salud
# Consentimiento para hacer una prueba para detectar arsénico

Como parte del Programa Comunitario de Salud VB/I7, estamos ofreciendo pruebas gratuitas para detectar arsénico en niños pequeños que viven dentro del Sitio del Superfund VB/I-70. El Departamento de Salud le recomienda que se examine la orina y el pelo de su hijo(a) para detectar arsénico si vive en una casa con niveles altos de arsénico en el suelo, o si las respuestas al cuestionario sobre riesgo de arsénico en el suelo indican que su hijo puede tener un riesgo en aumento por exposición al arsénico de su suelo. La exposición a niveles altos de arsénico se ha vinculado con numerosos riesgos a la salud, incluyendo problemas en el tracto digestivo y anormalidades en la piel (p.ej., decoloración y protuberancias anormales que pueden convertirse en cancerosas).

Trabajadores capacitados de salubridad tomarán una muestra de cabello de su hijo(a) y le darán instrucciones a usted para que ayude a su hijo a que proporcione una muestra de orina. Si su hijo no puede proporcionar una muestra de orina en el lugar de la prueba, le daremos instrucciones a usted para recolectar la muestra en su casa y le diremos cómo almacenarla hasta que la lleve. Para la prueba del cabello, se le cortará una porción pequeña de cabello (como del grueso de un lápiz) de la parte de atrás de la cabeza, de la nuca, en donde es menos visible.

Vamos a analizar las muestras de orina y de cabello sólo para ver el nivel de arsénico. Un coordinador de salubridad le enviará por correo los resultados de la prueba de su hijo. Usted recibirá los resultados de la prueba de su hijo en alrededor de tres semanas. Si encontramos que su hijo tiene demasiado arsénico en la orina o en el cabello, un coordinador de salubridad del Departamento de Salud del Estado se pondrá en contacto con usted. Se le puede pedir que haga que a su hijo se le haga otra prueba o se canalizará para recibir servicios gratuitos adicionales si se necesitan y si usted otorga su consentimiento. Esto puede incluir una investigación que haga de su casa de la Oficina de Salud Ambiental de Denver, o que la Agencia de Protección Ambiental (EPA) saque el arsénico de su patio.

Toda la información que usted proporcione se mantendrá confidencial. Su nombre, dirección, el nombre de su hijo y otra información de identificación **NO SE USARÁN** en ningún reporte que se publique ni se dará a ninguna persona que no sea usted y su departamento de salud local o estatal, sin su permiso por escrito.

**AUTORIZACIÓN PARA HACER LA PRUEBA DEL ARSÉNICO**: *He leído la información que antecede y entiendo los posibles inconvenientes de hacer que mi hijo proporcione una muestra de orina y de cabello. Estoy de acuerdo en la participación de:*

**NOMBRE DEL NIÑO** _____ **FECHA DE NACIMIENTO** _____ **LUGAR DE LA PRUEBA**

**DOMICILIO**_____ **CIUDAD** _____ **ZIP** _____

**TELEFONO** (_____)_____-_____ **NOMBRE DEL PADRE/MADRE (letra de imprenta)** _____

**CONTACTO DE EMERGENCIA** _____ **TELÉFONO DE EMERGENCIA** (____)____-_____

**PROVEEDOR O CLINICA PARA LA ATENCION MEDICA DEL NIÑO** _____

**FIRMA**_____ **FECHA**_____

Padre/madre o tutor adulto

**AUTORIZACIÓN PARA COMPARTIR LA INFORMACIÓN CON OTRAS DEPENDENCIAS DE SALUD:**: Si su hijo tiene un nivel alto de arsénico y usted califica para recibir servicios gratuitos adicionales, otras agencias pueden necesitar comunicarse con usted en relación con estos servicios. La información se compartirá sólo con la agencia apropiada que pueda proporcionarle un seguimiento a usted y a su familia.

*Al firmar abajo, doy permiso al Arsenic Exposure Investigation Team (incluyendo el Departamento de Salud del Estado, Denver Health and Hospitals, Denver Environmental Health y EPA) para que comparta la información sobre los niveles de arsénico de mi hijo y su dirección. Al compartir esta información, entiendo que estoy permitiendo que un representante de estas agencias se ponga en contacto conmigo en relación con estos servicios gratuitos de seguimiento. Este permiso permanecerá vigente durante un año a menos de que yo lo revoque. Entiendo que la participación en este programa de pruebas es voluntaria, y que si decido no firmar abajo, no perderé los beneficios o la atención médica a los que tengo derecho por otro concepto, y que a mi hijo de le harán las pruebas gratuitas del arsénico siempre que yo haya firmado la "AUTORIZACIÓN PARA HACER LA PRUEBA DEL ARSÉNICO" de la sección anterior.*

**FIRMA**_____ **FECHA** _____

Padre/madre o tutor adulto

Si quiere usted hacer alguna pregunta acerca de las pruebas del arsénico, llame a Jane Mitchell, del Departamento de Salud Pública y Medio Ambiente de Colorado, al 303-692-2644.

# Attachment 4

# Protocol for Sample Collection, Numbering, and Shipment

## PROTOCOL FOR DATA COLLECTION AND SAMPLE LABELING

This protocol identifies a method for data collection and sample labeling that minimizes redundant data entry and the potential for error.

***FOR EACH ADULT THAT COMES TO THE CLINIC WITH 1 OR MORE CHILDREN:***

### STEP 1. COMPLETE CHP FORM 1

- Obtain one set of VBI70 CHP forms (one set is used for each family).
- Assign a unique VBI70 case number to each child to be tested. Transfer the case number from the pre-printed sheet of labels to the appropriate box below each child's name on Form 1.
- Fill in the data for the family and each child that the family wishes to have tested.

***FOR EACH CHILD:***

### STEP 2. COMPLETE FORM 2 (one Form 2 for each child)

- Write the child name on the top of Form 2.
- Place the second label from the sheet of pre-printed labels on the appropriate box of Form 2.
- Collect the required data in Form 2, Part A

Based on the results from Form 2 Part A, recommend to adults what samples should be collected to evaluate arsenic exposure, if any.

- ***If arsenic testing is recommended*** and parent's consent is given for testing, proceed to complete Form 2 Part B. If arsenic testing is not recommended, proceed to Form 3.

### STEP 3. COMPLETE FORM 3 (one Form 3 for each child)

Write the child name on the top of Form 3.
Place the third label from the VBI70 CHP label sheet on the appropriate box of Form 3.

Record on the sheet which samples have been recommended and which they agree to. Be sure the appropriate consent form is signed before proceeding with sample collection.

## STEP 4. COLLECT SAMPLES

Blood

- Follow the standard procedure to obtain a filter-paper blood sample. Obtain a duplicate sample for about 1 in 20 cases, if blood flow is adequate and if the child is not distressed.

- For each sample collected, obtain one MedTox blood lead requisition form. For each sample, transfer large label from the bottom of the MedTox requisition to the MedTox pediatric lead collection card, and transfer the second smaller label to Form 3. **Enter VB id number** assigned to the child on the MedTox requisition form (in the field called Physician Provider No. VB_ _ _ _). Enter patient last name and DOB on the MedTox requisition.

- Record the number of blood samples successfully collected on Form 3.

Urine

- If a sample of urine is to be collected, provide the adult with a sample collection bottle and sample collection sheet. Ask them to assist the child in providing the sample. It is preferred that sample collection takes place in the clinic, but may occur in the home in some cases.

- For each urine sample collected, transfer the appropriate label from the pre-printed VBI70 CHP label sheet to the sample bottle and place the bottle in a cooler with blue ice.

Hair

- If a sample of hair is to be collected, collect the sample in accord with the standard procedure and attach the sample to the card provided by CTQ. Apply the appropriate label from the pre-printed VBI70 CHP label sheet to the card, place the card in a Ziploc bag, and store the sample until shipment to the lab.

## Step 5. SEND SAMPLES TO THE LAB

Blood Samples

Blood lead samples will be transferred daily to DHH. For each sample, collect and submit the following (as a package, to be placed in large Ziploc bag):

- The MedTox requisition
- The carbon copy of Form 1
- The carbon copy of the blood lead consent form
- The blood lead sample

Urine Samples

Complete a Chain of Custody (COC) form (provided as Form 4) for all urine samples to be submitted to the laboratory. Place the top copy of the COC in the cooler (chilled with blue ice) with the samples and send to the laboratory. Retain a copy of the COC for use by CDPHE.

Hair Samples

Complete a Chain of Custody (COC) form (provided as Form 5) for all hair samples to be submitted to the laboratory. Place the top copy of the COC in a mailing envelope along with the samples and send to the laboratory. Retain a copy of the COC for use by CDPHE.

# Attachment 5

# Protocol for PE Sample Collection

# PROTOCOL FOR INSERTION OF PE SAMPLES

This protocol identifies a method for inserting Performance Evaluation (PE) samples into the VBI70 CHP biomonitoring program sample streams. All PE samples should be inserted into the sample streams blind and in random order.

## BLOOD PE SAMPLES

Obtain a VBI70 forms kit and a MedTox requisition. Fill in Form 1, the blood consent form , and the MedTox requisition with fictitious information.

Transfer a VBI70 case number to Form 1 and to Form 3. Do not fill in Form 2.

For "Child Name" on Form 3, enter "PE". Indicate which type (nominal concentration) was used to prepare the sample.

Prepare the PE sample by placing a drop of blood from a CDC PE sample on the filter paper. Transfer one label from the MedTox requisition to the PE sample, and place the second MedTox label on Form 3.

## URINE PE SAMPLES

Obtain a VBI70 forms kit. Transfer a VBI70 case number to Form 1 and to Form 3.

On Form 1, simply enter "PE" for name. Do not fill in Form 2.

On Form 3, enter "PE" for "Child Name". Indicate which type (nominal concentration) of urine PE sample was used to prepare the sample.

Transfer the PE sample into a regular urine sample bottle. Transfer a urine label from the pre-printed sheet to the sample bottle.

## HAIR PE SAMPLES

Obtain a VBI70 forms kit. Transfer a VBI70 case number to Form 1 and to Form 3.

On Form 1, simply enter "PE" for name. Do not fill in Form 2.

On Form 3, enter "PE" for "Child Name". Indicate which type (nominal concentration) of hair PE sample was used to prepare the sample.

Transfer the PE sample onto a regular hair sample card. Transfer a hair label from the pre-printed sheet to the card.

# Attachment 6

# CTQ Internal Quality Control Procedures

# Intralaboratory and Interlaboratory Quality Control Procedure

## 1. SCOPE

This procedure applies to all analytical methods used in the laboratory.

It describes the rules governing the use of quality control, whether it is achieved through the use of certified reference materials (CRMs), reference materials (RMs), or interlaboratory comparison programs.

## 2. PRINCIPLES

Each series of analyses shall include at least one reference material to ensure the quality of the analyses and subsequently, the quality of the results submitted by the laboratory.

Intralaboratory quality control ensures that the quality of the results submitted by the laboratory is consistent.

Interlaboratory quality control enables the statistical comparison of the results of our methods and those of other laboratories around the world.

## 3. INTRALABORATORY QUALITY CONTROL PROCEDURE

### 3.1 General Procedure

Appropriate certified reference materials (CRM) and reference materials (RM) are listed in the "Quality Control" section of the analytical method.

Assay series are defined in the "Analytical Protocol" section of the analytical method, or on work sequence sheets related to each apparatus.

### 3.2 Analysis of Frequency and Number of Concentrations of CRMs and RMs to be Used

#### 3.2.1 Clinical and Metals Sectors

Generally, CRMs and RMs are analyzed as follows:

⇒ Analysis of one CRM or RM after establishing the calibration curve.
⇒ Analysis of one CRM or RM following every tenth sample and at the end of the series.

If various concentration levels are available, alternate analysis of these concentrations within the series.

#### 3.2.2 Environmental Sector

CRM or RM analysis frequency is defined in the analytical method protocol section.

Generally, one or two CRM or RM concentrations are used (depending on the method used).

3.3 Introduction of a New CRM or RM

Applies to all CRMs and RMs, whether the target value is temporary, definitive or not as yet established (when a new CRM or RM is introduced by overlapping it with the existing CRM or RM).

Procedure for the Introduction of a new CRM or RM:

1) In LIMS, enter the new CRM or RM via the "Static Cqs Sample Table" menu (Section 2.6 of the StarLIMS user manual).
2) In LIMS, modify the method description via the "Static Method Table" menu (Section 2.1 of the StarLIMS user manual).
3) In the analytical method, edit the "Quality Control" section to reflect the new CRM or RM.
4) In the electronic inventory, update the reference materials (see PL-036, Use of electronic inventory systems)
5) If applicable, modify the quality control values in all analytical apparatus software.

3.4 Compilation of CRM or RM Results

3.4.1 Entering CRM or RM Results in LIMS

Results are entered in LIMS via the "Results Entry" menu (Section 5 of the StarLIMS user manual) or the "Import" menu (Section 6)

Note: All CRM and RM results must be included in LIMS, even in the case of rejected series where CRM or RM results violate the rules outlined in 3.5.6.

3.4.2 Comments Associated With CRM or RM Results

Each time a CRM or an RM result is entered into LIMS, a comment may be added for background purposes. These comments may, for example, allow a user to quickly retrace the cause of a violation described in section 4.3. The comments may also include a pertinent explanation with regard to the analyzed series, or to the CRM or the RM. Each comment must be initialed by the person who prepared it. Each commentary associated with a red flag must be initialed by the chemist who conducted the analysis.

A comment must be written in each of the following situations:

⇒ Violation of a rule (red flag), whether results were submitted or not.
⇒ Changing one element of the method or changing an instrumental component.
For example:
- new CRM or RM batch, calibration standard, chemical, etc.
- new stock solution, working solution, or internal standard solution
- new preparation of a laboratory product (diazomethane, buffer solution, acid, base, etc.)
- new instrumental component (column, insert, lamp, septum, etc.)
- any changes to analytical protocol

⇒ Any other pertinent situation.
Comments associated with results are entered in LIMS via the "Results Entry" menu (section 5 of the StarLIMS user manual) or the "Import" menu (section 6).

3.5 Quality Control Chart and Table

Each CRM or RM has its own quality control chart and table.

### 3.5.1 Description of Quality Control Table

The table contains CRM and RM results that are used to create the chart, as well as several other pieces of pertinent information:

⇒ name of the compound or element and its code
⇒ name of the CRM or RM
⇒ analytical apparatus
⇒ date of analysis
⇒ results of CRM or RM measurements and units
⇒ ?trend point value?
⇒ relevant comments (see section 3.4.2)
⇒ relative (%) and absolute standard deviation for all CRM or RM results obtained.

### 3.5.2 Description of the Chart

The chart schematically lists the CRM or RM results that have been imported from LIMS.

The chart appears in the form of a graph where the x-axis represents the date of the CRM or RM analysis and the y-axis represents the value of the results of the CRM or RM analysis. The domain of the y-axis is +/- 5 standard deviations (+/- 5 sigma). All CRM or RM results which are not within +/- 5 standard deviations (+/- 5 sigma) do not appear on the chart, but may be found in the compiled results table that is attached to the chart. The x-axis allows for a maximum of 50 results to be recorded.

CRM or RM results are represented by black triangles which are not connected to each other. If many results are recorded on the same date, these results are superimposed. All results are included in the chart, even results from rejected series.

The centre line represents the target value of the CRM or RM. This value remains constant.

Bias, warning and action lines are drawn on either side of the centre line at +/- 1, +/- 2 and +/-3 standard deviations respectively. These lines remain constant.

The following information is included in the chart:

⇒ name of the compound or element and its code
⇒ name of the CRM or the RM
⇒ analytical apparatus
⇒ target value and units
⇒ the value of 1 sigma (standard deviation)
⇒ domain of the x-axis (from...to...)

For each CRM's or RM's result, a trend point is calculated as follows:

New trend point value = (0.8 x value of previous result) + (0.2 x value of new result)

Trend points do not appear on the chart. However, they are linked by the trend line, the purpose of which is to integrate data in order to show constancy or movement in the average.

Trend points are not calculated if the CRM's or RM's result is greater than +/- 3.5 standard deviations (considered an aberration), so as not to needlessly disrupt the trend line. In this case, the value of the previous trend point is duplicated.

The starting point of the trend line may be:

⇒ The CRM or RM target value if it is a new diagram or if there was a change in the method, which would result in a new trend line.
⇒ The last recorded trend point on the last control diagram.

### 3.5.3 Interpretation and Procedures

Each violation of the following rules appears in LIMS in the form of warning codes within the quality control table.
All rule violations must be the subject of a comment, as described in section 3.4.2.

All procedures undertaken to resolve an issue stemming from the violation of a rule must be recorded. In simple cases, a comment as described in section 3.4.2 is sufficient. When the method must be modified, form F-10-09 (Method, procedure or protocol development summary) must be completed as well.

### 3.5.4 Code Green

No violation of the rules. Results may be submitted without further verification.

### 3.5.5 Code Yellow

The series is not rejected as a result of the rule violation. However, particular care must be used to solve the problem, if applicable (checking that all steps of the method are under control).

1-"Trend": The trend line crosses the bias line (+/- 1 standard deviation).
2-"2 SIG": A CRM or an RM result is past the warning line (+/- 2 standard deviations).

### 3.5.6 Code Red

The series is usually rejected as a result of the rule violation. A solution must be sought and implemented, and the analysis must be repeated.

All series containing a code red flag that are accepted must include a comment and a justification as described in section 3.4.2.

1-"3 SIG": A CRM or an RM result is past the action line (+/- 3 standard deviations)
2-"2 OOS": Two consecutive CRM or RM results are past the same warning line (either +2 standard deviations or -2 standard deviations).
3-"4 SIG": Two consecutive CRM or RM results are separated by a total of 4 standard deviations, within a domain of +/- 3 standard deviations (for example, one result is between + 2 and +3 standard deviations and the other is between -2 and -3 standard deviations).
4-"4 OOS" Four consecutive CRM or RM results are past the same bias line (either +1 standard deviation or -1 standard deviation).
5-"TARGET" Ten consecutive CRM or RM results are on the same side of the target value.

SIG: sigma
OOS: out of specification

3.6 Archiving Completed CRM or RM Charts and Data

Use the following procedure to archive completed CRMs or RMs:

1. In LIMS, follow the archiving procedure in the "Static Cqs Sample Table" menu (section 2.6 of the StarLIMS user manual)
2. In the analytical method, edit the "Quality Control" section to reflect the new CRM or RM.
3. In the electronic inventory, update the reference materials (see PL-036, Use of electronic inventory systems).

## 4. PARTICIPATION IN EXTERNAL QUALITY ASSESSMENT PROGRAMS

### 4.1 List of Programs in which the Laboratory Participates

#### 4.1.1 Clinical

| Program | Area of Expertise |
|---|---|
| College of American Pathologists: Serum Alcohol | Acetone, ethanol, isopropanol, methanol |
| College of American Pathologists: Toxicology | General toxicology, serum/urine |
| College of American Pathologists: Forensic Urine Drug Testing | Amphetamines, cannabinoids, cocaine, phencycladine, opiates |
| *Société Québécoise de biochimie clinique: SQBC* [Quebec society of clinical biology] | Acetaminophen, diphenylhydantoin, phenobarbital |
| American Association of Bioanalysts: TDM | Valproic acid, carbamazepine, diphenylhydantoin, ethosuximide, phenobarbital, primidone |
| German Society of Occ. Medicine and Env. Medicine | Urinary cotinine |

#### 4.1.2 Environmental

| Program | Area of Expertise |
|---|---|
| FIOH Quality Assurance Program for organic solvent metabolites, Finland | Phenol, trichloroacetic acid, 2,5-hexanedione, muconic acid in urine |
| German Society of Occ. Medicine and Env. Medicine | Hippuric acid, pentachlorophenol, mandelic acid and phenylglyoxylic acid in urine.<br>Congeneric PCBs in plasma and pp'-DDE, pp'-DDT, hexachlorobenzene, B-BHC and lindane (y-HCH). |
| QUASIMEME, United Kingdom | PCBs and organochlorines in tissues |
| AMAP Ring Text for PCBs and OCs | Congeneric PCBs and organochlorine-based pesticides in plasma |

#### 4.1.3 Metallic

| Program | Area of Expertise |
|---|---|
| Blood lead laboratory reference system (BLLRS), CDC Atlanta | Pb in blood |
| *Centre de toxicologie du Québec* Interlaboratory Comparison Program | Al (se), As (ur), Cd (bl), Cd (ur), Cr (ur), Cu (se), Cu (ur), F (ur), Hg (bl), Hg (ur), Pb (bl), Pb (ur) Se (se), Se (ur), Zn (se) |
| *Centre de toxicologie du Québec* ICP-MS Comparison Program | Al, Be, Bi, Cd, Co, Cu, Cr, Hg, Mn, Mo, Ni, Pb, Sb, Se, Sn, Sr, Te, Ti, Tl, V, W, Zn |
| Interlaboratory mercury comparisons, Health Canada, Ottawa | Hg in hair |
| State of New York Department of Health | Pb in blood, ZPP, multielement screen serum |

| | |
|---|---|
| Wisconsin State Laboratory of Hygiene | Pb in blood, ZPP |
| Worldwide Interlaboratory Aluminum Quality Control, France | Al in water and serum |
| German Society of Occ. Medicine and Env. Medicine | Hg and Mn in blood, Cr, Cu, Mn, Se and Zn in serum, As, Be, Hg, Mn, Tl and (As speciation) urine |

4.2 Procedure

Materials provided by various programs are processed at the same time as routine analyses. Results are recorded on answer sheets and mailed or faxed to the agency responsible for managing the program, except for tests conducted through the PCI and the ICP-MS programs.

Results are compared with our own upon reception of statistics compiled by the managing agency. When results do not fall within established standards, the method is reevaluated and corrected if necessary under the supervision of the chemist responsible for the analysis. Answer sheets and documents provided by the managing agency are kept in each laboratory.

For programs managed by our laboratory (PCI, ICP-MS and AMAP Ring Test for PCBs and OCs), results are recorded on an answer sheet and given to the person responsible for data entry. These programs (PCI, ICP-MS and AMAP Ring Test) all have separate result reports.

5. REFERENCES

(1) Quality Assurance of Chemical Measurements. Lewis Publishers, John Keenan Taylor, 1987, 328 p.

(2) Nadkami, R. A., The Quest for Quality in the Laboratory, Anal Chem, 1991; 63(13): 675-682.

(3) Westgard, J. O., Multirule and "Westgard Rules": What Are They? http://www.westgard.com, 2001.